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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/526,802	03/16/2000	Jagdish Parasrampur	4600-0131.30	1577

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EXAMINER

QAZI, SABIHA NAIM

ART UNIT	PAPER NUMBER
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1616

DATE MAILED: 06/14/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/526,802

Applicant(s)

PARASRAMPURIA ET AL.

Examiner

Sabiha Naim Qazi

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on 07 May 2002.
- 2a) ☒ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☐ Claim(s) 1-10 and 36-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-8, 10 and 36-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 9 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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**Office Action on Merits**

*Instant invention is drawn to formulations and method of use of form I polymorph and form II polymorph of dihydroepiandrosterone (DHEA).*

Claims 1-10 and 36-39 are pending.

No claim is allowed.

Claims 1-8, 10 and 36-39 are examined; others are withdrawn from consideration as non-elected invention.

Response filed in paper no. 13 is hereby acknowledged. Rejection under 103 (a) is maintained. Arguments were fully considered but are not found persuasive. Even if prior art does not teach specific polymorphic forms they are not patentable over the other form. In composition or formulation once the compound is in solution it is not differentiated by the polymorphic forms.

Claim 1-8,10 and 36-39 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "comprising" cited in claims is inclusive and fails to exclude unrecited steps. The use of the term comprising to introduce claimed structure means that the ingredients covered by these claims may involve more elements than those positively recited. *Ex parte Gottzein et al.*, 168 USPQ 176 (PTO Bd. App. 1969). Comprising leaves the claim open for inclusion of unspecified ingredients even in major amounts. *Ex parte Davis et al.*, 80 USPQ 448 (PTO Bd. App. 1948).

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Claims 1-8, 10 and new claims 36-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Morales et al. (US 5,407,927) and Loria et al. (US 5,077,284) in combination of Chang et al. (DN 123:265915, HCAPLUS, abstract of J. Pharm. Sci. (1995), 84(10), 1169-79). These references teach formulations, methods and polymorphic forms of DHEA, which embraces Applicant's claimed invention. See the entire documents especially lines 37-62, col. 1; lines 4-10 and lines 59-66, col. 12 in US 5,077,284 and lines 59-68, col. 2; lines 25-58, col. 3 and table 2 in col. 7 in US 5,407,927. These references teach the formulation of DHEA for various methods of treatments.

Chang et al. teaches solid state crystallization of DHEA and its polymorph (forms I-III). Furthermore, it discloses that form I is more stable than others. See abstract in the article AQ in form 1449. Instant claims differ from the reference in claiming formulations and method of preparation of specific polymorphic form I of DHEA.

It would have been obvious to one skilled in the art at the time when instant invention was made, to be motivated to prepare additional beneficial preparations and formulations of DHEA by using any polymorphic form of this compound especially form I and would expect the same results because when the compositions of the compound would be prepared, it would be the same after dissolving in the solvent, no matter what polymorphic form exists in the solid state. Motivation is to prepare formulations, of DHEA form I polymorph because form I is taught to be more stable, for the treatment of systemic lupus erythematosus, to prevention or reduction of loss of bone density, and treatment of chronic fatigue syndrome or fibromyalgia. One would expect same properties with the polymorphic form I of DHEA formulation. Different polymorphic forms are not patentable over each other in absence of unexpected properties.

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It had been held that by changing the form, purity or other characteristics of an old product does not render the novel form patentable where the difference in form, purity or characteristic was inherent in or rendered obvious by the prior art. *In re Cofer*, 53 CCPA (1966) 830, 835, 354 F2d 664, 668, 148 USPQ 268, 271.

In the light of the forgoing discussion, the Examiner's ultimate legal conclusion is that the subject matter defined by the instant claims would have been obvious within the meaning of 35 U.S.C. 103(a).

***Telephone Inquiry Contacts***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Naim Qazi whose telephone number is 703-305-3910. The examiner can normally be reached on First Friday Off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jose Dees can be reached on 703-308-4628. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

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June 11, 2002



SABIHA QAZI, PH.D  
PRIMARY EXAMINER